

7-09-04

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PTO/SB/21 (02-04)

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/760,100	
	Filing Date	January 16, 2004	
	First Named Inventor	Jonathan C. HELLER et al.	
	Art Unit	1641	
	Examiner Name	Unassigned	
Total Number of Pages in This Submission		Attorney Docket Number	29191-707.501

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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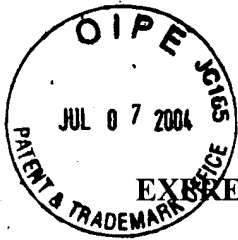
Firm or Individual name	U.P. Peter Eng, Reg. No. 39,666, WILSON SONSINI GOODRICH & ROSATI		
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PATENT

Attorney Docket No. 29191-707.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	<u>PATENT APPLICATION</u>
)	
Inventor(s): Jonathan C. HELLER et al.)	
)	Art Unit: 1641
Application No.: 10/760,100)	
)	Examiner: Unassigned
Filed: January 16, 2004)	
)	
Title: Assay Customization)	
)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
- ☒ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Forms PTO-1449 are enclosed herewith. Due to the voluminous nature of the references, each reference is provided in PDF format on the attached CD ROM, clearly titled by publication number or author.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29191-707.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: _____

7/6/04

By: _____

U.P. Peter Eng, Reg. No. 39,666

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/760,100
				Filing Date	January 16, 2004
				First Named Inventor	Jonathan C. HELLER et al.
				Art Unit	1641
				Examiner Name	Unassigned
Sheet	1	of	6	Attorney Docket Number	29191-707.501

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-5,227,471	07-13-1993	Wright, Jr.	
		US-5,314,996	05-24-1994	Wright, Jr.	
		US-5,639,656	06-17-1997	Wright, Jr.	
		US-6,157,921	12-05-2000	Barnhill	
		US-6,207,370-B1	03-27-2001	Little et al.	
		US-6,306,087-B1	10-23-2001	Barnhill et al.	
		US-6,309,816-B1	10-30-2001	Zhang et al.	
		US-6,363,383-B1	03-26-2002	Kindo et al.	
		US-6,427,141-B1	07-30-2002	Barnhill	
		US-6,558,955-B1	05-06-2003	Kristal et al.	
		US-6,658,395-B1	12-02-2003	Barnhill	
		US-6,675,104-B1	01-06-2004	Paulse et al.	
		US-6,714,925-B1	03-30-2004	Barnhill et al.	
		US-2002/0095260-A1	07-18-2002	Huyn	
		US-2002/0138208-A1	09-26-2002	Paulse et al.	
		US-2002/0193950-A1	12-19-2002	Gavin et al.	
		US-2003/0004402-A1	01-02-2003	Hitt et al.	
		US-2003/0013120-A1	01-16-2003	Patz, Jr. et al.	
		US-2003/0077611-A1	04-24-2003	Slepnev	
		US-2003/0132114-A1	07-17-2003	Mischak et al.	
		US-2003/0134304-A1	07-17-2003	van der Greef et al.	
		US-2003/0148295-A1	08-07-2003	Wan et al.	
		US-2003/0148922-A1	08-07-2003	Knapp et al.	
		US-2003/0228639-A1	12-11-2003	Wright et al.	
		US-2004/0005634-A1	01-08-2004	Patz, Jr. et al.	
		US-2004/0018519-A1	01-29-2004	Wright, Jr.	
		US-2004/0029194-A1	02-12-2004	Parish et al.	
		US-2004/0043436-A1	03-04-2004	Vlahou et al.	
Examiner Signature				Date Considered	

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² - Number ² - Kind Code ² (if known)				
		WO-95/25281-A1	09-21-1995	Univ. of Washington		
		WO-01/25791-A2	04-12-2001	Ciphergen Biosystems, Inc.		
		WO-01/36977-A2	05-25-2001	Matritech, Inc.		
		WO-01/57263-A1	08-09-2001	Advion Biosciences, Inc.		
		WO-01/57518-A2	08-09-2001	Yolbolsum Canada Inc.		
		WO-01/71360-A2	09-27-2001	Eastern Virginia Medical School		
		WO-02/04957-A2	01-17-2002	Esperion Therapeutics, Inc.		
		WO-02/08760-A1	01-31-2002	Biotron Limited		
		WO-02/97703-A2	12-05-2002	Emili, Andrew et al.		
		WO-02/27329-A2	04-04-2002	Eastern Virginia Medical School		
		WO-02/46448-A2	06-13-2002	Eastern Virginia Medical School		
		WO-03/14302-A2	02-20-2003	MDS Proteomics, Inc.		
		WO-03/31031-A1	04-14-2003	Ciphergen Biosystems, Inc. et al.		
		WO-03/38055-A2	05-08-2003	MDS Proteomics, Inc.		
		WO-03/42774-A2	05-22-2003	Caprion Pharmaceuticals, Inc.		
		WO-03/72710-A2	09-04-2003	Eastern Virginia Medical School		
		WO-03/83442-A2	10-09-2003	Perlegen Sciences, Inc.		
		WO-03/91695-A2	11-06-2003	Johns Hopkins Univ.		
		WO-03/97799-A2	11-27-2003	Eastern Virginia Medical School		
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Sheet	3	of	6	Attorney Docket Number	29191-707.501
NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
		ADKINS, Joshua N., et al., "Toward a human blood serum proteome: analysis by multidimensional separation coupled with mass spectrometry". The American Society for Biochemistry and Molecular Biology, Inc., MCP Paper (November 15, 2002)			
		ANDERSON, Leigh, et al., "A comparison of selected mRNA and protein abundances in human liver". Electrophoresis (1997), 18:533-537.			
		ANDERSON, N. Leigh, et al., "The Human Plasma Proteome". Molecular & Cellular Proteomics (2002), 1:845-867.			
		BANEZ, Lionel L., et al., "Diagnostic potential of serum proteomic patterns in prostate cancer". The Journal of Urology (2003) 170:442-446.			
		BILLINGSLEY, Janice, "Research offers hope in fight against ovarian cancer". Health & Science (Feb 8, 2002) 3 pages.			
		CAO, Ping et al., "Analysis of peptides, proteins, protein digests, and whole human blood by capillary electrophoresis/electrospray ionization-mass spectrometry using an in-capillary electrode sheathless interface". J Am Soc Mass Spectrometry (1998), 9:1081-1088.			
		CAZARES, L. H., et al., "Normal, benign, preneoplastic, and malignant prostate cells have distinct protein expression profiles resolved by surface enhanced laser desorption/ionization mass spectrometry". Clinical Cancer Research (August 2002) 8:2541-2552.			
		CBS News, "Setback for a silent killer". CBS News.com (April 2, 2002), 2 pages.			
		CRISP - Computer retrieval of information on scientific projects [abstract], << ">http://commons.clt.nih.gov/crisp3/CRISP_LIB.getdoc?textkey=6388327&p_grant_num=5R01HG002033-03&p_query=&ticket=... >>. Downloaded May 9, 2002, 2 pages.			
		DIAMANDIS, Eleftherios P., "Point proteomic patterns in biological fluids: do they represent the future of cancer diagnostics?". Clinical Chemistry (2003) 49(8)1272-1278.			
		EDITORIAL, "Proteomic diagnostics tested". Nature (June 3, 2004), 429(3)487.			
		ETZIONI, Ruth, et al., "Combining biomarkers to detect disease with application to prostate cancer". Biostatistics (2003), 4(4)523-538.			
		ETZIONI, Ruth, et al., "The case for early detection". Nature Reviews/Cancer (April 2003), 3:1-10.			
		GERACIMOS, A., "Outwitting Ovarian Cancer". Correlogic Systems, Inc., Press Release dated April 16, 2002, 4 pages.			
Examiner signature				Date Considered	

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
		GYGI, Steven P., "Correlation between protein and mRNA abundance in yeast". Molecular and Cellular Biology (March 1999) 1720-1730.			
		HARAN, Christine, "The promise of proteins - Do these tricky molecules hold the answers to cancer?". (October 2---) 43-46.			
		HARRISON, Harold H., et al., "Multiple serum protein abnormalities in carbohydrate-deficient glycoprotein syndrome: pathognomonic finding of two-dimensional electrophoresis?". Clinical Chemistry (1992), 38:1390-1392.			
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		HILARIO, Melanie, et al., "Machine learning approaches to lung cancer prediction from mass spectra". Proteomics (2003) 3:1716-1719.			
		HOLLON, Tom "Software Zeroes in on ovarian cancer". The Scientist (April 15, 2002) 16(8):16.			
		JOHANNES, Laura, "Tiny protein may lead to better screen test for prostate cancer". Dow Jones (Nov. 4, 2003), 1-2.			
		LEHRER, S., et al., "Putative protein markers in the sera of men with prostatic neoplasms". BJU International (2003) 92:223-225.			
		LEVINE, Peter, "Correlogic's ovarian cancer test nears market introduction". Diagnostic Testing and Technology Report (July 2003) 1:5-7.			
		MARKEY, Mia K., et al. "Decision tree classification of proteins identified by mass spectrometry of blood serum samples from people with and without lung cancer". Proteomics (2003) 3:1678-1679.			
		MARSHALL, John, et al., "Processing of serum proteins underlies the mass spectral fingerprinting of myocardial infraction". Journal of Proteome Research (January 20, 2003) 12 pages.			
		MIAN, Shahid, et al., "A prototype methodology combining surface-enhanced laser desorption/ionization protein chip technology and artificial neural network algorithms to predict the chemoresponsiveness of breast cancer cell lines exposed to Paclitaxel and Doxorubicin under in vitro conditions". Proteomics (2003) 3:1725-1737.			
		MILLER, Jeremy C., et al., "Antibody microarray profiling of human prostate cancer sera: Antibody screening and identification of potential biomarkers". Proteomics (2003) 3:56-63.			
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NON PATENT LITERATURE DOCUMENTS					
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		NEVILLE, Padraic, et al., "Generalizable mass spectrometry mining used to identify disease state biomarkers from blood serum". Proteomics (2003) 3:1710-1715.			
		PUROHIT, Parul V., et al., "Discriminant models for high-throughput proteomics mass spectrometer data". Proteomics (2003) 3:1699-1703.			
		QU, Yinsheng, et al., "Boosted decision tree analysis of surface-enhanced laser desorption/ionization mass spectral serum profiles discriminates prostate cancer from noncancer patients". Clinical Chemistry (2002), 48(10):1835-1843.			
		RUBIN, Rita, "Blood test may spot ovarian cancer earlier". Health & Science (Feb 8, 2002) 2 pages.			
		SCHULTZ, Gary A. et al., "Development of a proteome marker model for ovarian cancer using direct analysis of diluted serum by automated nanoelectrospray TOFMS". ASMS (2003) 2 pages.			
		SILVA, Chris, "Small company, big partners - Bethesda-based Correlogic Systems enlists allies in quest to bring its concern detection test to market". Washington Business Journal (Aug 30-Sep 5, 2002) 2 pages.			
		SOMORJAI, R. L., et al., "Class prediction and discovery using gene microarray and proteomics mass spectroscopy data: curses, caveats, cautions". Bioinformatics (2003) 19(12):1484-1491.			
		SORACE, James M., et al., "A data review and re-assessment of ovarian cancer serum proteomic profiling". BMC Bioinformatics (2003) 4(24):1-13.			
		SORLIE, Therese, et al., "Gene expression patterns of breast carcinomas distinguish tumor subclasses with clinical implications". PNAS (September 11, 2001), 98(19):10869-10874.			
		SVEDBERG, Målin, et al., "Sheathless electrospray from polymer microchips". Anal. Chem. (2003) 75:3934-3940.			
		TOUCHETTE, Nancy, "Diagnosing Ovarian Cancer by Proteomics". Genome News Network (2003), 2 pages.			
		VAN 'T VEER, Laura, et al., "Gene expression profiling predicts clinical outcome of breast cancer". Nature (January 2002) 415:530-536.			
		VLAHOU, Antonia, et al., "Development of a novel proteomic approach for the detection of transitional cell carcinoma of the bladder in urine". American Journal of Pathology (April 2001), 158(4):1491-1502.			
Examiner signature				Date Considered	

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				Application Number	10/760,100	
				Filing Date	January 16, 2004	
				First Named Inventor	Jonathan C. HELLER et al.	
				Art Unit	1641	
				Examiner Name	Unassigned	
Sheet	6	of	6	Attorney Docket Number		29191-707.501
NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
		VOHRADSKY, J., "Adaptive classification of two-dimensional gel electrophoretic spot patterns by neural networks and cluster analysis". Electrophoresis (1997), 18:2749-2754.				
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